## IN THE

# Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA.

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER,
MAINE DEPARTMENT OF HUMAN SERVICES, AND
G. STEVEN ROWE, ATTORNEY GENERAL OF MAINE,
Respondents.

\*

## On Writ of Certiorari to the United States Court of Appeals for the First Circuit

#### JOINT APPENDIX

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PETITION FOR CERTIORARI FILED JULY 31, 2001 CERTIORARI GRANTED JUNE 28, 2002

# TABLE OF CONTENTS

District Court Docket Entries	Page 1
Court of Appeals Docket Entries	20
Complaint for Declaratory, Injunctive and Other Relief, <i>Pharmaceutical Research &amp; Mfrs. of Am.</i> v. Concannon, No. 00-157-B-H (D. Me. filed Aug. 10, 2000)	35
Feldman Decl. (Aug. 8, 2000)	49
Bantham Decl. (Aug. 9, 2000)	52
Bilyk Decl. (Aug. 9, 2000)	55
McPhillips Decl. (Aug. 9, 2000)	75
Tempel Decl. (Aug. 9, 2000)	86
Howell Aff. (Aug. 9, 2000)	102
Moules Aff. (Aug. 9, 2000)	109
Defendants' Answer, <i>Pharmaceutical Research &amp; Mfrs. of Am. v. Concannon</i> , No. 00-157-B-H (D. Me. filed Sept. 11, 2000)	137
Clifford Aff. (Sept. 7, 2000)	147
Richardson Aff. (Sept. 7, 2000)	153
Concannon Aff. (Sept. 8, 2000)	165

TABLE OF CONTENTS—continued	D
Transcript of Proceedings, Hearing on Preliminary Injunction, <i>Pharmaceutical Research &amp; Mfrs.</i>	Page
of Am. v. Commissioner, No. 00-157-B-H (D. Me. Oct. 19, 2000)	183
Plaintiff's Letter Brief, <i>Pharmaceutical Research &amp; Mfrs. of Am. v. Concannon</i> , No. 00-157-B-H (D. Me. Oct. 23, 2000)	221
Defendants' Letter Brief, <i>Pharmaceutical Research &amp; Mfrs. of Am. v. Concannon</i> , No. 00-157-B-H (D. Me. Oct. 23, 2000)	226
Pharmaceutical Research & Mfrs. of Am. v. Commissioner, No. 00-157-B-H (D. Me. Dec. 14, 2000) (order denying motion to intervene)	231
Statutes Section 1927 of the Social Security Act, 42 U.S.C. §§ 1396, 1396a(a)(10)(A)-(C), (a)(19), (a)(30)(A)-(B) & (a)(54), 1396c, 1396d(a) & 1396r-8(g)	236
Maine Medical Assistance Manual, Proposed Rules, chs. II & III, § 80 (2000) (appendices omitted)	261
Maine Rx Program, Proposed Rule: Rules of the Department of Human Services, ch. 130, § 1 (2000)	307

# TABLE OF CONTENTS—continued

## **NOTICE**

The following documents have been omitted in the printing of this Joint Appendix. They may be found in the Petitioners' Appendix to the 01-188 Petition For A Writ Of Certiorari at the following pages:

following pages:	
Pharmaceutical Research & Mfrs. of Am. Concannon, 249 F.3d 66 (1st Cir. 2001)	
Pharmaceutical Research & Mfrs. of Am. Concannon, No. 00-2446 (1st Cir. June 13, 200 (order denying rehearing en banc)	01)
Pharmaceutical Research & Mfrs. of Am. Commissioner, No. 00-157-B-H (D. Me. Oct. 2000) (order granting motion for preliminal injunction)	26, ary
Statutes 42 U.S.C. § 1396r-8 (in pertinent part)Ay An Act to Establish Fairer Pricing for Prescrition Drugs, 2000 Me. Legis. Ch. 786 (S 1026) (L.D. 2599)	ip- .P.

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## MAINE DISTRICT COURT

#### 1:2000cv00157

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

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COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES, et al.,

Defendants.

#### **DOCKET ENTRIES**

DATE	NO.	PROCEEDINGS
8/10/00	1	COMPLAINT filed; FILING FEE \$ 150 RECEIPT # 41094 (Service of Process Deadline 12/8/00 ) (hdj) [Entry date 08/11/00]
8/10/00	2	MOTION by PHARMACEUTICAL RESEA for Leave to File memo in excess of page limits (hdj) [Entry date 08/11/00]
8/10/00	3	MOTION with memorandum in support by PHARMACEUTICAL RESEA for Preliminary Injunction (hdj) [Entry date 08/11/00]
8/10/00	4	AFFIDAVIT of Russel A. Bantham (hdj) [Entry date 08/11/00]
8/10/00	5	AFFIDAVIT of Richard A. Feldman (hdj) [Entry date 08/11/00]
8/10/00	6	AFFIDAVIT of George Bilyk (hdj) [Entry date 08/11/00]

DATE	NO.	PROCEEDINGS
8/10/00	7	AFFIDAVIT of Thomas M. McPhillips (hdj) [Entry date 08/11/00]
8/10/00	8	AFFIDAVIT of Judith L. Tempel (hdj) [Entry date 08/11/00]
8/10/00	9	AFFIDAVIT of David Moules (hdj) [Entry date 08/11/00]
8/10/00	10	AFFIDAVIT of Scott Howell, M.D. (hdj) [Entry date 08/11/00]
8/10/00		SUMMONS(ES) issued for HS, ME COMMN, ATTORNEY GENERAL, ME (hdj) [Entry date 08/11/00]
8/11/00		CORPORATE DISCLOSURE STATE- MENT per Local Rule 83.7 by PHARMACEUTICAL RESEA (hdj)
8/11/00		Pro Hac Vice Certificate for PHARMA-CEUTICAL RESEA by DANIEL M. PRICE, ALLEN S. RUGG (hdj)
8/11/00		ENDORSEMENT on Motion granting [2-1] motion for Leave to File memo in excess of page limits (/s/For the Court, Harriett D. Jefferson, Deputy Clerk) cc: cnsl (hdj)
8/16/00	_	RETURN of Service Executed as to HS, ME COMMN, ATTORNEY GENERAL, ME 8/11/00 Answer due on 8/31/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
8/23/00	<del></del>	MOTION during telephone conference by HS, ME COMMN, ATTORNEY GEN- ERAL, ME to Extend Time to file answer and response to preliminary injunction motion (jgw)

DATE	NO.	PROCEEDINGS
8/23/00	11	REPORT of Conference of Counsel granting in part [0-0] oral motion to Extend Time to file answer and response to preliminary injunction motion, reset Answer deadline to 9/11/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN, Response to Motion reset to 9/11/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN for [3-1] motion for Preliminary Injunction (signed by MAG. JUDGE MARGARET J. KRAVCHUK) cc: cnsl (jgw) PORTLD STNDRD
9/11/00	12	MOTION by HS, ME COMMN, ATTORNEY GENERAL, ME for Leave to File response in excess of page limits (jgw)
9/11/00	13	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [3-1] motion for Preliminary Injunction; Reply to Response due 9/21/00 for PHARMA-CEUTICAL RESEA (jgw)
9/11/00	14	AFFIDAVIT of Kevin Concannon (jgw)
9/11/00	15	AFFIDAVIT of Timothy S. Clifford, M.D. (jgw)
9/11/00	16	AFFIDAVIT of Buritt Richardson, Jr., M.D. (jgw)
9/11/00	17	ANSWER to Complaint by HS, ME COMMN, ATTORNEY GENERAL, ME (jgw)

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DATE	NO.	PROCEEDINGS
9/12/00		ENDORSEMENT on Motion granting [12-1] motion for Leave to File response in excess of page limits ( signed by Walentine, DC for JUDGE D. B. HORNBY ) cc: cnsl (jgw)
9/20/00	18	Letter MOTION by HS, ME COMMN, ATTORNEY GENERAL, ME for Order granting protection from hearing or o/a from 9/27 to 10/13 (err)
9/20/00		Motion(s) taken under advisement: [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13 under advisement (err)
9/21/00	_	Pro Hac Vice Certificate for PHARMA-CEUTICAL RESEA by KATHLEEN M. SULLIVAN (jgw)
9/21/00	19	MOTION by PHARMACEUTICAL RESEA for Leave to File reply brief in excess of page limits (jgw)
9/21/00	20	REPLY by PHARMACEUTICAL RESEA to response to [3-1] motion for Preliminary Injunction (jgw)
9/21/00		ENDORSEMENT on Motion granting [19-1] motion for Leave to File reply brief in excess of page limits ( signed by Walentine, DC for JUDGE D. B. HORNBY ) cc: cnsl (jgw)
9/21/00	21	MOTION by PHARMACEUTICAL RESEA for Hearing on [3-1] motion for Preliminary Injunction (jgw)

DATE	NO.	PROCEEDINGS
9/21/00		Motion(s) taken under advisement: [21-1] motion for Hearing on [3-1] motion for Preliminary Injunction under advisement (jgw)
9/26/00	22	Letter RESPONSE by PHARMA-CEUTICAL RESEA to [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13; Reply to Response due 10/6/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw) [Entry date 09/27/00] PORTLD STNDRD
9/28/00	_	ENDORSEMENT on Motion granting [21-1] motion for Hearing on [3-1] motion for Preliminary Injunction, granting [18-1] motion for Order granting protection from hearing or o/a from 9/27 to 10/13, Motion Hearing Set Re: [3-1] motion for Preliminary Injunction set for 9:00 10/19/00 ( signed by Deputy Clerk, Marie Cross for JUDGE D. B. HORNBY ) cc: cnsl (mmc)
10/3/00	23	ORDER (re: the Hearing set for 10/19/00 on the Motion for Preliminary Injunction), set Telephone Conference for 3:30 10/17/00 (re: final hearing on the merits, factual disputes, etc.) ( signed by JUDGE D. B. HORNBY) cc: cnsl (mmc)
10/17/00		Tele-conference re: held. The Court has determined that the parties will proceed on the Preliminary Injunction Argument only on 10/19/00. ( Court Reporter: Pauline Terry) before JUDGE D. B. HORNBY (mmc) [Entry date 10/19/00]

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DATE	NO.	PROCEEDINGS
10/19/00	<del></del>	Motion(s) taken under advisement: [3-1] motion for Preliminary Injunction under advisement (mmc)
10/19/00		MOTION Hearing held re: [3-1] motion for Preliminary Injunction before JUDGE D. B. HORNBY. Any further filings shall be filed by 10/23/00. ( Court Reporter: Pauline Terry) (mmc)
10/20/00	24	TRANSCRIPT filed of HEARING ON #3, MOTION FOR PRELIMINARY INJUNCTION for dates of: 10/19/2000, held before Judge D. BROCK HORNBY ( Court Reporter: PAULINE TERRY) (dw)
10/23/00	25	MOTION (no objection) by MAINE COUNCIL OF SEN, VIOLA QUIRION for Leave to File Brief of amicus curiae (mmc)
10/23/00	26	AFFIDAVIT of John Moran (mmc)
10/23/00	27	AFFIDAVIT of Viola Quirion (mmc)
10/23/00	28	BRIEF filed by MAINE COUNCIL OF SEN, VIOLA QUIRION (mmc)
10/23/00	29	BRIEF filed by HS, ME COMMN, ATTORNEY GENERAL, ME (mmc)
10/23/00	30	BRIEF filed by PHARMACEUTICAL RESEA (mmc) PORTLD STNDRD
10/26/00	31	ORDER granting by agreement [25-1] motion for Leave to File Brief of amicus curiae, granting [3-1] motion for Preliminary Injunction. The Commisioner is here by preliminarily enjoined from penalizing manufacturers, by placing their drugs on

DATE	NO.	PROCEEDINGS
		prior listing status, for refusing to negotiate or to pay a rebate to Maine's RX program. The Attorney General is hereby preliminarily enjoined from seeking to enforce the illegal profiteering portion of the statute against transactions that occur outside the State of Maine, even of the presciption drugs eventually end up and are ultimately purchased in Maine. So Ordered. ( signed by JUDGE D. B. HORNBY ) cc: cnsl (mmc)
11/9/00	32	NOTICE OF INTERLOCUTORY APPEAL of [31-1] order by HS, ME COMMN, ATTORNEY GENERAL, ME FILING FEE \$ 105 RECEIPT # 41921 (bfa)
11/9/00	_	CERTIFICATE of Clerk (Form 83) Org docs #: 1-32 (bfa)
11/9/00	_	Certified and transmitted record on appeal to U.S. Court of Appeals: [32-1] interlocutory appeal by ATTORNEY GENERAL, ME, HS, ME COMMN (bfa)
11/13/00	33	MOTION with memorandum in support by VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE to Intervene; Response to Motion due 12/1/00 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (mjl)
11/13/00	34	AFFIDAVIT of Viola Quirion (mjl)
11/13/00	35	AFFIDAVIT of Michelle Campbell (mjl)

DATE	NO.	PROCEEDINGS
11/13/00	36	AFFIDAVIT of John Moran (mjl)
11/13/00	37	AFFIDAVIT of Richard J. Donahue, M.D. (mjl)
11/22/00	38	MOTION with memorandum in support by VIOLA QUIRION, MICHELLE CAMPBELL, RICHARD DONAHUE to Extend Time to file a Notice of Appeal (mnm)
12/1/00	39	RESPONSE by PHARMACEUTICAL RESEA to [33-1] motion to Intervene; Reply to Response due 12/11/00 for RICHARD DONAHUE, for MAINE COUNCIL OF SEN, for MICHELLE CAMPBELL, for VIOLA QUIRION (mnm)
12/4/00	_	USCA Case Number Re: interlocutory appeal USCA NUMBER: 00-2446 (jgw)
12/4/00	40	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [33-1] motion to Intervene-(The defendants do not object to the motion to intervene filed by the Maine Council of Senior Citizens, et al. We will not be filing a memorandum in response to that motion.) (mnm) [Entry date 12/06/00] PORTLD STNDRD
12/11/00	41	REPLY by VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE to response to [33-1] motion to Intervene (dw)
12/11/00	_	Motion(s) taken under advisement: [33-1] motion to Intervene under advisement (dw)

DATE	NO.	PROCEEDINGS
12/14/00	42	ORDER denying [33-1] motion to Intervene-For these reasons, the motion to intervene is Denied and the motion for extention of time to file a notice of appeal is Denied because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiffs complaint ( signed by JUDGE D. B. HORNBY ) cc: cnsl (mnm) [Entry date 12/15/00]
12/14/00	_	ENDORSEMENT on Motion denying [38-1] motion to Extend Time to file a Notice of Appeal-see order #42 dated 12/14/00-The motion to intervene is DENIED and the motion for extension of time to file a notice of appeal is DENIED because I have denied the motion to intervene. No action is necessary on the motion to alter or amend judgment and to dismiss Count V of the plaintiff's Complaint ( signed by JUDGE D. B. HORNBY ) cc: cnsl (mnm) [Entry date 12/19/00]
4/9/01	43	MOTION to Intervene by EDWIN D SCHINDLER on behalf of plaintiff; Response to Motion due 4/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
4/27/01	44	RESPONSE by PHARMACEUTICAL RESEA to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff; Reply to Response due 5/8/01 for EDWIN D SCHINDLER (mlh)

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DATE	NO.	PROCEEDINGS
4/30/01	45	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff; Reply to Response due 5/11/01 for EDWIN D SCHINDLER (mmc) [Entry date 05/01/01]
5/7/01	47	MOTION by EDWIN D SCHINDLER for Clarification of Page Limit Set by Local Rule 7(c) and, if necessary for Leave to File reply in excess of page limit; Response to Motion due 5/29/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (mlh)
5/7/01	48	REPLY by EDWIN D'SCHINDLER to response to [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff (mlh)
5/7/01		Motion(s) taken under advisement: [47-1] motion for Clarification of Page Limit Set by Local Rule 7(c) under advisement, [47-2] motion for Leave to File reply in excess of page limit under advisement, [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff under advisement (mlh) PORTLD STNDRD
5/7/01	46	SUPPLEMENTAL FILING by EDWIN SCHINDLER in Support of His Pending Motion for Intervention (mlh) [Entry date 05/08/01]

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DATE	NO.	PROCEEDINGS
5/18/01	49	OPINION of USCA re: [32-1] interlocutory appeal Decision: District Court is reversed and the temporary injunction is vacated. (Mandate Deadline set for 6/18/01) (ckb) [Entry date 05/21/01]
5/21/01	50	MOTION by EDWIN D SCHINDLER for Expedited Order on pending motion to intervene; Response to Motion due 6/11/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN (jgw)
6/8/01	51	ORDER ON EDWIN D. SCHINDLER'S MOTION TO INTERVENE denying [43-1] motion to Intervene by EDWIN D SCHINDLER on behalf of plaintiff ( signed by JUDGE D. B. HORNBY ) cc: cnsl (dw)
6/8/01		ENDORSEMENT on Motion terminating [47-1] motion for Clarification of Page Limit Set by Local Rule 7(c), granting [47-2] motion for Leave to File reply in excess of page limit ( signed by JUDGE D. B. HORNBY ) cc: cnsl (mmc) [Entry date 06/11/01]
6/8/01		ENDORSEMENT (see order issued on 6/8/01 denying motion to intervene) on Motion granting [50-1] motion for Expedited Order on pending motion to intervene ( signed by JUDGE D. B. HORNBY ) cc: cnsl (mmc) [Entry date 06/12/01]
6/12/01	52	MOTION by EDWIN D SCHINDLER for Reconsideration of [51-1] order denying #43 Motion to Intervene; Response to

DATE	NO.	PROCEEDINGS
		Motion due 7/3/01 for RICHARD DONA-HUE, for MAINE COUNCIL OF SEN, for MICHELLE CAMPBELL, for VIOLA QUIRION, for VIOLA QUIRION, for MAINE COUNCIL OF SEN, for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (err)
6/20/01	53	MEMORANDUM by EDWIN D SCHIN- DLER in support of [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (bld)
6/25/01	54	RESPONSE to by PHARMACEUTICAL RESEA to supplemental memo in support of [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene; Reply to Response due 7/6/01 for EDWIN D SCHINDLER (jgw) [Entry date 06/29/01]
6/29/01	55	REPLY by EDWIN D SCHINDLER to response to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (jgw)
6/29/01	56	RESPONSE by ATTORNEY GENERAL, ME to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene; Reply to Response due 7/10/01 for EDWIN D SCHINDLER (dw) PORTLD STNDRD

DATE	NO.	PROCEEDINGS
7/2/01	57	REPLY by EDWIN D SCHINDLER to response (#56) to [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene (jgw) [Entry date 07/05/01]
7/5/01		Motion(s) taken under advisement: [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene under advisement (jgw)
7/5/01	58	NOTICE OF INTERLOCUTORY APPEAL of [51-1] order denying mtn to intervene by EDWIN D SCHINDLER FILING FEE \$ 105.00 RECEIPT # 43186 (jgw)
7/6/01	59	Amended NOTICE OF INTERLOCU- TORY APPEAL of [51-1] order denying mtn to intervene by EDWIN D SCHINDLER FILING FEE \$ 105.00 RECEIPT # 43190 (jgw)
7/10/01		ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene ( signed by JUDGE D. B. HORNBY ) cc: cnsl (jgw)
7/10/01		COPIES of Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)

DATE	NO.	PROCEEDINGS
7/10/01		CLERK'S SUPPLEMENTAL CERTIFI- CATE (re: [59-1] interlocutory appeal, [58-1] interlocutory appeal ); 1ST sup- plemental certificate; Orig. documents numbered: 33-59 (jgw)
7/10/01		Transmitted supplemental record on appeal: [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER (jgw)
7/11/01	_	Deadline updated as Order issued in USCA staying entry of Mandate; reset Mandate deadline to 8/10/01 (jgw)
7/16/01	_	USCA Case Number Re: [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER USCA NUMBER: 01-2006 (jgw)
7/17/01	60	SECOND AMENDED NOTICE OF INTERLOCUTORY APPEAL of [0-0] order ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene, [51-1] order by EDWIN D SCHINDLER FILING FEE \$ 105.00 RECEIPT # 43207 (jgw) [Edit date 07/20/01]
7/20/01		CLERK'S SUPPLEMENTAL CERTIFI- CATE (re: [60-1] interlocutory appeal); 2nd supplemental certificate; Orig. docu- ments numbered: 60 (jgw)

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DATE	NO.	PROCEEDINGS
7/20/01		Transmitted supplemental record on appeal: [60-1] interlocutory appeal by EDWIN D SCHINDLER (jgw) PORTLD STNDRD
7/20/01		COPIES of 2nd amended Notice of Appeal sent to counsel. Parties: PHARMA-CEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)
7/23/01	61	MOTION by EDWIN D SCHINDLER to Stay proceedings pending appeal of district court Order denying mtn to intervene; Response to Motion due 8/13/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMACEUTICAL RESEA (jgw)
8/13/01		Deadline updated; reset Mandate deadline to 8/17/01 (err)
8/13/01	62	RESPONSE by PHARMACEUTICAL RESEA to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene; Reply to Response due 8/24/01 for EDWIN D SCHINDLER (err)

DATE	NO.	PROCEEDINGS
8/13/01	63	RESPONSE by HS, ME COMMN, ATTORNEY GENERAL, ME to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene; Reply to Response due 8/24/01 for EDWIN D SCHINDLER (mmc) [Entry date 08/14/01]
8/16/01	64	REPLY by EDWIN D SCHINDLER to Dfts' response to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/16/01	65	REPLY by EDWIN D SCHINDLER to pltf's response to [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/16/01		Motion(s) taken under advisement: [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene under advisement (jgw)
8/20/01	66	(NOTICE) MEMORANDUM by EDWIN D SCHINDLER in support of [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene (jgw)
8/20/01		ENDORSEMENT on Motion denying [61-1] motion to Stay proceedings pending appeal of district court Order denying mtn to intervene "Denied. (There are no proceedings currently pending before this court.)" ( signed by JUDGE D. B. HORNBY ) cc: cnsl (mnm) [Entry date 08/21/01]

DATE	NO.	PROCEEDINGS
8/24/01	67	NOTICE OF INTERLOCUTORY APPEAL to the Federal Circuit Court of Appeals of [0-0] order ENDORSEMENT on Motion denying [52-1] motion for Reconsideration of [51-1] order denying #43 Motion to Intervene, [51-1] order by EDWIN D SCHINDLER FILING FEE \$ 105.00 RECEIPT # 43249 (jgw) PORTLD STNDRD
8/24/01		COPIES of Notice of Appeal sent to counsel. Parties: PHARMACEUTICAL RESEA, HS, ME COMMN, ATTORNEY GENERAL, ME, MAINE COUNCIL OF SEN, VIOLA QUIRION, VIOLA QUIRION, MICHELLE CAMPBELL, MAINE COUNCIL OF SEN, RICHARD DONAHUE, EDWIN D SCHINDLER (jgw)
8/29/01	68	ORDER from U.S. Court of Appeals rescinding Order dated August 13, 2001 issuing mandate (jgw)
8/29/01	69	ORDER from U.S. Court of Appeals denying motion to stay mandate by amicus curiae Edwin R. [sic] Schindler (jgw)
9/4/01	_	U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT; Case Number Re: [67-1] interlocutory appeal by EDWIN D SCHINDLER USCA NUMBER: 01-1597 (jgw)
9/4/01	_	Deadline updated; reset Mandate deadline to 9/11/01 (err)

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DATE	NO.	PROCEEDINGS
9/13/01		Deadline updated; reset Mandate deadline to 9/17/01 (bld)
9/18/01		Deadline updated; reset Mandate deadline to 10/1/01 (jgw)
9/19/01	70	MANDATE/JUDGMENT OF USCA (certified copy) dated 8/13/01 Re: [32-1] interlocutory appeal by ATTORNEY GENERAL, ME, HS, ME COMMN Decision: Judgment of USDC reversed and temporary injunction vacated (please refer to USCA Order #68 rescinding issuance of this mandate) (jgw) [Entry date 09/21/01]
10/9/01	71	MOTION by EDWIN D SCHINDLER to Intervene by EDWIN D SCHINDLER to appeal anticipated entry of final judgment against PhRMA; Response to Motion due 10/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMA-CEUTICAL RESEA (jgw) [Entry date 10/10/01] [Edit date 10/10/01]
10/9/01	72	MOTION by EDWIN D SCHINDLER to Stay proceedings in USDC pending appeal in Federal Circuit; Response to Motion due 10/30/01 for ATTORNEY GENERAL, ME, for HS, ME COMMN, for PHARMA-CEUTICAL RESEA (jgw) [Entry date 10/10/01]

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DATE	NO.	PROCEEDINGS
10/10/01	73	WITHDRAWAL of [71-1] motion to Intervene by EDWIN D SCHINDLER to appeal anticipated entry of final judgment against PhRMA, [72-1] motion to Stay proceedings in USDC pending appeal in Federal Circuit (jgw)
10/22/01	74	MANDATE/JUDGMENT OF Federal Circuit Court (certified copy) Re: [67-1] interlocutory appeal by EDWIN D SCHINDLER Decision: Maine dfts mtn to dismiss this appeal granted; Schindler's motions are moot; Schindler's petition for writ of mandamus is denied (jgw) [Edit date 10/22/01] PORTLD STNDRD
10/30/01	75	Interlocutory MANDATE/JUDGMENT OF USCA (certified copy) Re: [60-1] interlocutory appeal by EDWIN D SCHINDLER, [59-1] interlocutory appeal by EDWIN D SCHINDLER, [58-1] interlocutory appeal by EDWIN D SCHINDLER Decision: Appeal DISMISSED (err) [Entry date 10/31/01] [Edit date 10/31/01]
5/28/02	76	MOTION by PHARMACEUTICAL RESEA for Allen S. Rugg to Withdraw as Counsel (err)
5/29/02		ENDORSEMENT on Motion granting [76-1] motion for Allen S. Rugg to Withdraw as Counsel ("Granted. Other counsel have appeared.") ( signed by MAG. JUDGE MARGARET J. KRAVCHUK ) cc: cnsl (err)

# UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

## No. 00-2446

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellee,

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v.

COMMISSIONER, MAINE DEPARTMENT OF HUMAN SERVICES; ATTORNEY GENERAL, ME Defendants-Appellants.

## **DOCKET ENTRIES**

DATE	PROCEEDINGS
11/22/00	CIVIL CASE docketed. Opening forms sent. Notice filed by Appellants Commissioner, and Attorney General, ME. Appearance form due 12/6/00. Docketing Statement due 12/6/00. [00-2446] (cmpa) [00-2446]
11/22/00	RECORD filed: 1 volume(s). Transcript of Hearing on Preliminary Injunction included. [516840-1] [00-2446] (cmpa) [00-2446]
11/29/00	TRANSCRIPT REPORT/ORDER filed by Appellants Commissioner and Attorney General, ME. Transcript is already on file in the Clerk's office. [00-2446] (cmpa) [00-2446]
11/29/00	BRIEFING SCHEDULE. Appellant's Brief due 1/8/01. Appendix due 1/8/01. Appellee's Brief due 2/7/01. Reply brief due 2/21/01. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
11/30/00	MOTION filed by Appellant Commissioner of the Maine Department of Human Services and Attorney General, ME to expedite appeal. Certificate of service 11/28/00. [00-2446] (cmpa) [00-2446]
11/30/00	APPEARANCE filed by Kathleen M. Sullivan for Appellees Pharmaceutical Research Pharmaceutical and Manufacturers of America. [518686-1] [00-2446] (cmpa) [00-2446]
11/30/00	APPEARANCE filed by Andrew S. Hagler for Appellants Attorney General, ME, and Commissioner. [519912-1] [00-2446] (cmpa) [00-2446]
11/30/00	DOCKETING STATEMENT, filed by Appellants Commissioner and Attorney General, ME. [00-2446] (cmpa) [00-2446]
12/4/00	DISCLOSURE STATEMENT on behalf of Appellee Pharmaceutical Resea filed. [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by Bruce C. Gerrity for Appellee Pharmaceutical Research. [519891-1] [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by Allen S. Rugg for Appellee Pharmaceutical Research. [519894-1] [00-2446] (cmpa) [00-2446]
12/4/00	APPEARANCE filed by John R. Brautigam for Appellants Attorney General, ME, and Commissioner. [519896-1] [00-2446] (cmpa) [00-2446]

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DATE	PROCEEDINGS
12/5/00	RESPONSE filed by Appellee Pharmaceutical Research to motion to expedite appeal [518606-1]. Parties agree on briefing schedule. Certificate of service dated 12/5/00 [519953-1] [00-2446] (cmpa) [00-2446]
12/5/00	APPEARANCE filed by Daniel M. Price for Appellee Pharmaceutical Research. [519957-1] [00-2446] (cmpa) [00-2446]
12/11/00	ORDER filed. Appellants' motion for an expedited appeal is granted to the extent set out in the parties' agreed upon briefing schedule. That is, appellants' brief will be due by January 8, 2001, appellee's brief shall be filed within thirty days of the date of the filing of appellants' brief, and appellants' reply brief will be due within fourteen days of the filing of appellee's brief. If the briefs are filed according to this schedule, then oral argument will be scheduled for the court's March 2001 sitting. (ciny) [00-2446]
12/11/00	BRIEFING SCHEDULE. Appellant's Brief due 1/8/01. Appendix due 1/8/01. Appellee's Brief due 2/7/01. Reply brief due 2/21/01. [00-2446] (ciny) [00-2446]
12/11/00	LETTER filed by Thomas C. Bradley on behalf of the Maine Citizen Leadership Fund informing the court that a motion to intervene was filed on their behalf in the district court. [00-2446] (kati) [00-2446]

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DATE	PROCEEDINGS
1/9/01	BRIEF filed by Appellant Attorney General, ME and Appellant Kevin Concannon. Pages: 60. Copies: 10, delivered by mail. Certificate of service date 01/08/01. [526780-1] Appellee brief due 2/8/01. [00-2446] (karn) [00-2446]
1/9/01	ELECTRONIC DOCUMENT filed by Appellant Commissioner and Appellant Attorney General, ME. [00-2446] (karn) [00-2446]
1/9/01	APPENDIX filed by Appellant Commissioner and Appellant Attorney General, ME. Copies: 5. Volumes: 1. Delivered by mail, filed. Certificate of service date 1/8/01. [526805-1] [00-2446] (karn) [00-2446]
1/17/01	APPEARANCE filed by Thomas Charles Bradley for Amicus Curiae Richard Donahue, Amicus Curiae Michelle Campbell. [529329-1] [00-2446] (mlyn) [00-2446]
1/17/01	APPEARANCE filed by Arn H. Pearson for Amicus Curiae Richard Donahue, Amicus Curiae Michelle Campbell, Amicus Curiae Viola Quirion, Amicus Curiae Maine Council. [529333-1] [00-2446] (mlyn) [00-2446]
1/17/01	MOTION filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue to file appendix. Certificate of service dated 1/16/01. [00-2446] (mlyn) [00-2446]
1/18/01	PARTY Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue added to case. [00-2446] (mlyn) [00-2446]

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DATE	PROCEEDINGS
1/18/01	ORDER filed granting motion of the Amicus parties to file an appendix. [00-2446] (mlyn) [00-2446]
1/18/01	BRIEF filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue in support of appellants. Pages: 29, Copies: 9, delivered by mail. Certificate of service date 1/16/01. [529342-1] [00-2446] (mlyn) [00-2446]
1/18/01	APPENDIX filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue. Copies: 5. Volumes: 1. Delivered by mail, filed. Certificate of service date 1/16/01. [529343-1] [00-2446] (mlyn) [00-2446]
1/22/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Maine Council, Amicus Curiae Viola Quirion, Amicus Curiae Michelle Campbell, Amicus Curiae Richard Donahue. To replace original disk sent with Amicus brief. Original was in MS Word. [00-2446] (cmpa) [00-2446]
1/24/01	Assigned for the month of March, (3/5/01). [00-2446] (ceca) [00-2446]
2/1/01	ATTORNEY Marinn F. Carlson for Appellee Pharmaceutical Research added to case. [00-2446] (cmpa) [00-2446]
2/1/01	APPEARANCE filed by Marinn F. Carlson for Appellee Pharmaceutical Resea. [534128-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
2/8/01	BRIEF filed by Appellee Pharmaceutical Research. Pages: 40, Copies: 10, delivered by mail. Certificate of service date 2/7/01. [534738-1] Reply brief due 2/22/01. [00-2446] (cmpa) [00-2446]
2/9/01	PARTY Abbott Laboratories, AMGEN, Inc., Bristol-Myers, Glaxo Wellcome PLC, Smithkline Beecham, Johnson & Johnson, Merck Company, Pfizer, Inc., Procter & Gamble Co., Schering Corp added to case. These companies are part of Pharmaceutical Research and Manufacturers of America. [00-2446] (tim) [00-2446]
2/12/01	MOTION filed Edwin D. Schindler. "Motion for Leave to File Amicus Curiae Brief in Support of Plaintiff-Appellee Seeking Affirmance, and for Participation in Oral Argument, Pursuant to Fed.R.App.P. 29(b) and (g)" Certificate of service dated 2/10/01. [00-2446] (cmpa) [00-2446]
2/14/01	RESPONSE faxed and filed by Appellee Pharmaceutical Research. "Response to Amicus Curiae Schindler's Motion for Leave to Participate in Oral Argument" [535686-1]. Certificate of service dated 2/14/01 [536689-1] [00-2446] (cmpa) [00-2446]
2/15/01	BRIEF filed by Amicus Curiae Chamber of Commerce of the United States in support of Appellee Pharmaceutical Research and Manufacturer of America. Pages: 19, Copies: 9, delivered by mail. Certificate of service date 2/14/01. [536917-1] [00-2446] (cmpa) [00-2446]

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DATE	PROCEEDINGS
2/15/01	PARTY Added. Amicus Curiae Chamber of Commerce added to case. [00-2446] (cmpa) [00-2446]
2/15/01	DISCLOSURE STATEMENT on behalf of Amicus Curiae Chamber of Commerce of the United States filed. [00-2446] (cmpa) [00-2446]
2/16/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Chamber of Commerce. Disk of Amicus brief. [00-2446] (cmpa) [00-2446]
2/16/01	RESPONSE filed by Appellant Commissioner, Maine Department of Human Services and Attorney General, ME. "Memorandum in Opposition to Motion of Edwin D. Schindler for Leave to File an Amicus Curiae Brief" Certificate of service dated 2/15/01 [537228-1] [00-2446] (cmpa) [00-2446]
2/16/01	PARTY ADDED. Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. added to case. [00-2446] (cmpa) [00-2446]
2/16/01	DISCLOSURE STATEMENT on behalf of Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, and Amicus Curiae 60 Plus Assoc. filed. [00-2446] (cmpa) [00-2446]

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DATE	PROCEEDINGS
2/16/01	ELECTRONIC DOCUMENT filed by Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. Disk to Amicus Curiae Brief. [00-2446] (cmpa) [00-2446]
2/16/01	BRIEF filed by Amicus Curiae Washington Legal, Amicus Curiae Allied Educational, Amicus Curiae International Patien, Amicus Curiae Kidney Cancer Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae 60 Plus Assoc. in support of Appellee Pharaceutical Research. Copies: 10, delivered by mail. Certificate of service date 2/14/01. [538082-1] [00-2446] (cmpa) [00-2446]
2/20/01	RESPONSE filed by Edwin D. Schindler. "Reply Memorandum of Amicus Curiae Edwin Schindler on Motion for Leave to File Amicus Brief" Certificate of service dated 2/19/01 [537538-1] [00-2446] (cmpa) [00-2446]
2/21/01	APPEARANCE filed by Richard A. Samp and Daniel J. Popeo for Amicus Curiae 60 Plus Assoc., Amicus Curiae Seniors Coalition, Amicus Curiae Kidney Assoc., Amicus Curiae International Patien, Amicus Curiae Allied Educational, Amicus Curiae Washington Legal. [538154-1] [00-2446] (cmpa) [00-2446]
2/22/01	APPEARANCE filed by Steven J. Rosenbaum for Amicus Curiae Chamber of Commerce. [538348-1] [00-2446] (karn) [00-2446]

DATE	PROCEEDINGS
2/22/01	ELECTRONIC DOCUMENT (brief on disk) filed by Appellants Commissioner and Attorney General, ME. [00-2446] (frnk) [00-2446]
2/23/01	ORDER filed. Upon consideration of "Motion For Leave To File Amicus Curiae Brief In Support Of Plaintiff-Appellee Seeking Affirmance, And For Participation In Oral Argument, Pursuant To Fed. R. App. P. 29(b) and (g)," It is ordered that the motion to file an Amicus Brief is hereby granted. The request to participate in oral argument is denied. [00-2446] (bety) [00-2446]
2/23/01	PARTY Amicus Curiae Edwin D. Schindler added to case. [00-2446] (bety) [00-2446]
2/23/01	Brief of Amicus Curiae Edwin D. Schindler in support of plaintiff-appellee seeking affirmance. Pages: 36, (5,969 words) Copies: 10, delivered by mail. Certificate of service date 2/12/01. [538836-1] [00-2446] (bety) [00-2446]
2/23/01	REPLY BRIEF filed by Appellant's Commissioner and Attorney General, ME. Pages: 29, Copies: 10, delivered mail. Certificate of service date 2/22/01. [538878-1] [00-2446] (frnk) [00-2446]
2/27/01	APPEARANCE filed by Steven J. Rosenbaum for Amicus Curiae Chamber of Commerce of the United States. [539456-1] [00-2446] (cmpa) [00-2446]
2/27/01	APPEARANCE filed for Amicus Curiae Edwin D. Schindler, pro se. [541125-1] [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
3/5/01	CASE ARGUED 03/05/01. Bownes, Keeton, Saris, JJ. (ceca) [00-2446]
5/16/01	OPINION filed. Senior Circuit Judge Bownes, District Court Judge Keeton, and District Court Judge Saris. Signed Judge Hugh H. Bownes, aut PUBLISHED. [563283-1] [00-2446] (cmpa) [00-2446]
5/16/01	JUDGMENT entered by Senior Circuit Judge Bownes, District Court Judge Keeton, and District Court Judge Saris closing case. The Judgment of the district court is reversed and the temporary injunction is vacated. [563284-1] [00-2446] (cmpa) [00-2446]
5/30/01	PETITION filed by Appellee Pharmaceutical Research and Manufacturers of America's for rehearing en banc. [567137-1] [00-2446] Certificate of Service dated 5/29/01. [00-2446] (mlyn) [00-2446]
6/7/01	LETTER filed by Computer Research Services. Research firm writes, "Please forward copies of the following documents" [00-2446] (cmpa) [00-2446]
6/12/01	SUPPLEMENTAL AUTHORITY pursuant to FRAP 28j filed by Appellee Pharmaceutical Research. Certificate of Service 6/11/01 [00-2446] (cmpa) [00-2446]

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#### **DATE**

#### **PROCEEDINGS**

6/13/01

ORDER. Senior Circuit Judge Hugh H. Bownes, District Court Judge Robert E. Keeton, District Court Judge Patti B. Saris. The panel that heard this case has voted to deny the petition for panel rehearing. For the following reasons, there can be no action taken on the petition for rehearing en banc. None of the members of the panel are eligible to vote on the petition for rehearing en banc. Federal Rule of Appellate Procedure 35(a) provides in pertinent part: When Hearing or Rehearing En Banc May Be Ordered. A majority of the circuit judges who are in regular active service may order that an appeal or other proceeding be heard or reheard by the court of appeals en banc. See United States v. Leichter, 167 F.3d 667 (1st Cir. 1999) (absolute majority of active judges is needed to grant rehearing en banc). -2- Judges Keeton and Saris are United States District Court Judges and Judge Bownes is a Senior Circuit Court Judge. All of the active Circuit Court Judges with the exception of Chief Judge Torruella have recused themselves from this case. The petition for rehearing en banc must, therefore, be denied. Chief Judge Torruella wants to be recorded as voting "in favor of rehearing en banc, based on the opinion of the District Court." Judgment shall issue in accord with the Rules. [00-2446] (cmpa) [00-2446]

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6/19/01

MOTION filed by Appellee Pharmaceutical Research. "Plaintiff-Appelee's Motion to Stay the Mandate Pending Filing of a Petition for Writ of Certiorari." [572393-1] Certificate of service dated 6/19/01. [00-2446] (cmpa) [00-2446]

DATE	PROCEEDINGS
6/29/01	Defendants-appellants' opposition to plaintiff-appellee's motion to stay the mandate [572393-1]. Certificate of service dated 6/28/01 [574576-1] [00-2446] (bety) [00-2446]
7/3/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes, District Court Judge, and District Court Judge Robert E. Keeton. Mandate is stayed for 28 days to July 31, 2001. (cmpa) [00-2446]
7/13/01	RECORD filed: 2 vol(s). Documents 33-59. Filed in lead case 00-2446. [577814-1] [01-2006, 00-2446] (cmpa) [00-2446 01-2006]
7/17/01	MOTION filed by Appellant Edwin D. Schindler. "Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals for the Federal Circuit" Certificate of Service dated 07/16/01. (cmpa) [00-2446]
7/25/01	MOTION filed by Amicus Curiae Edwin D. Schindler. "Motion to Stay Mandate Pending Determination on Pending Motion to Dismiss for Lack of Appellate Jurisdiction" to further stay mandate until 7/24/01 Certificate of service dated 7/24/01. [00-2446] (cmpa) [00-2446]
7/30/01	RESPONSE filed by Attorney General, ME. LETTER filed by State of Maine. The Attorney General's Office responds to the motions Edwin Schindler has filed in 00-2446 and 01-2006. Certificate of service dated 7/27/01 [581972-1] [00-2446, 01-2006] (cmpa) [00-2446 01-2006]

DATE	PROCEEDINGS
7/30/01	REPLY filed by Amicus Curiae Edwin D. Schindler. "Reply to Maine's Letter of July 27, 2001 on the Pending Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals for the Federal Circuit" Certificate of service dated 7/28/01 [581982-1] [00-2446] (cmpa) [00-2446]
7/31/01	LETTER filed by Daniel M. Price. Appellee PhRMA has filed a Petition for a Writ of Certiorari at the United States Supreme Court. Counsel writes that "PhRMA's filing today in Washington D.C. automatically extends that stay until the Supreme Court disposes, of the petition." [00-2446] (cmpa) [00-2446]
8/3/01	U.S. SUPREME COURT NOTICE filed regarding petition for writ of certiorari. Filed in the Supreme Court on [583793-1] 08/01/01. Supreme Court case number: 01-188. [00-2446] (cmpa) [00-2446]
8/13/01	ORDER filed by Chief Judge Hugh H. Bownes. Upon consideration of "Motion to Dismiss for Lack of Appellate Jurisdiction or, in the Alternative, for Transfer to the United States Court of Appeals the Federal Circuit" and response, It is hereby ordered that said motion is denied. (cmpa) [00-2446]
8/13/01	ORDER filed by Chief Judge Hugh H. Bownes. Upon consideration of the motion to further stay mandate and response, it is ordered that said motion be denied. (cmpa) [00-2446]

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DATE	PROCEEDINGS
8/13/01	MANDATE ISSUED. [00-2446] (cmpa) [00-2446]
8/13/01	RECORD retained for companion case number(s): 01-2006. Record remains filed under 00-2446. [00-2446] (cmpa) [00-2446]
8/21/01	MOTION filed by Appellee Pharmaceutical Resea in 00-2446 to recall mandate. Certificate of service dated 8/20/01. [00-2446] (cmpa) [00-2446]
8/27/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes. The Order of August 13, 2001 issuing the mandate is hereby rescinded. (cmpa) [00-2446]
8/27/01	ORDER filed by Senior Circuit Judge Hugh H. Bownes. The Motion to Stay Mandate filed by Amicus Curiae Edwin R. [sic] Schindler is hereby denied. (cmpa) [00-2446]
5/13/02	PUBLIC NOTE: "Notice of Change of Address" Daniel M. Price and Marinn F. Carlson have moved their practices to the law firm of Sidley Austin Brown & Wood LLP in Washington, D.C. their new address is: Sidley Austin Brown & Wood LLP, 1501 K Street NW, Washington, D.C. 20005. Tel: 202-736-8000 Fax: 202-736-8711. [00-2446] (cmpa) [00-2446]
5/20/02	ATTORNEY MOTION filed by Allen S. Rugg for Appellee Pharmaceutical Research. "Motion for Leave to Withdraw" Certificate of service dated 5/17/02. [00-2446] (cmpa) [00-2446]

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DATE	PROCEEDINGS
5/22/02	ORDER. Leave is hereby granted Attorney Allen S. Rugg to withdraw as counsel for the appellee, Pharmaceutical Research & Manufacturers of America. (cmpa) [00-2446]
7/5/02	U.S. SUPREME COURT ORDER granting petition for writ of certiorari filed in the Supreme Court on 06/28/02. (cmpa) [00-2446]
7/15/02	RECORD returned to originating court. Debbie Whitney at the district court has requested that this record be sent back. The mandate has not issued. ** Documents 1-60; Hearing on Preliminary Injunction held on 10/19/00 ** (cmpa) [00-2446]

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA 1100 Fifteenth Street, N.W. Washington, DC 20005 Plaintiff,	* * * * * *	
v.	*	Civil Action No
KEVIN CONCANNON, in his official	*	
capacity as Commissioner of the Department of Human Services	*	
for the State of Maine	*	
221 State Street Augusta, Maine 04333	*	
ANDREW METERPER in his efficient	*	
ANDREW KETTERER, in his official capacity as Attorney General for the	*	
State of Maine	*	
6 State House Station	*	
Augusta, Maine 04333	*	
Defendants.	*	
Determants.	*	

# COMPLAINT FOR DECLARATORY, INJUNCTIVE AND OTHER RELIEF

Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), by its undersigned attorneys, states in support of this Complaint as follows:

#### INTRODUCTION

- 1. This is an action for declaratory, injunctive and other relief brought by PhRMA against Defendant Kevin Concannon, the Commissioner of the Department of Health and Human Services of the State of Maine, in his official capacity, and against Defendant Andrew Ketterer, Attorney General of the State of Maine, in his official capacity. Plaintiff seeks injunctive and declaratory relief barring the implementation and enforcement of specified provisions of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter the "Act," provisions hereinafter cited to Section of 22 M.R.S.A., copy attached as Exhibit A hereto), and declaring them unlawful.
- 2. The challenged provisions of the Act (1) require drug manufacturers to finance drug discounts to Maine residents, and threaten to restrict Maine Medicaid beneficiaries' access to the manufacturers' drugs; (2) punish drug manufacturers for charging prices and realizing profits that the State deems to be excessive, even in out-of-state transactions; and (3) punish drug manufacturers for rearranging their affairs so as to minimize their exposure to these provisions of the Act while continuing to ensure that their drugs will be available to Maine residents.
- 3. The challenged provisions of the Act violate the Commerce Clause of the United States Constitution by regulating transactions that occur outside Maine, by tying the discounts that drug manufacturers must provide for drugs dispensed in Maine to price discounts provided in other jurisdictions, and by preventing drug manufacturers from modifying their channels of distribution in response to the Act.
- 4. The challenged provisions of the Act also violate the Supremacy Clause of the United States Constitution by imposing restrictions on patients' access to manufacturers'

drugs in the federal Medicaid program to punish manufacturers who do not participate in the new Maine drug program.

#### **PARTIES**

- 5. Plaintiff, PhRMA, is a non-profit corporation, organized and existing under the laws of the State of Delaware.
- 6. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies account for more than 75 percent of brand name drug sales in the United States.
- 7. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.
- 8. All of PhRMA's members have their principal places of business outside Maine. By far the greatest part of PhRMA's members' prescription drug sales are to wholesalers and other entities located outside Maine. With limited exceptions, PhRMA's members are not parties to sales transactions occurring in, or with purchasers in or from, the state of Maine.
- 9. PhRMA brings this suit on behalf of its members. At least one of PhRMA's members possesses standing to sue in

its own right; the regulation of prescription drug pricing is of vital concern to PhRMA's members; and neither the claim asserted nor the relief demanded necessitates the participation of individual PhRMA members.

- 10. Defendant Kevin Concannon is the Commissioner of the Department of Human Services (hereinafter the "Department") for the State of Maine. Defendant Concannon is sued in his official capacity only.
- 11. Pursuant to the Act, Defendant Concannon (hereinafter, the "Commissioner") is responsible, directly and through his Department, for the implementation and, in substantial part, enforcement of the Act.
- 12. Defendant Andrew Ketterer is the Attorney General of the State of Maine. Defendant Ketterer is sued in his official capacity only.
- 13. Pursuant to the Act, Defendant Ketterer (hereinafter, the "Attorney General") is responsible for the enforcement of the profiteering provisions of the Act.

#### JURISDICTION

- 14. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1343 because this case arises under the Constitution and laws of the United States.
- 15. This Court has authority to grant declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202.

#### **VENUE**

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) because the Defendants maintain their offices within this judicial district and because the events giving rise to the claims herein occurred within this judicial district.

#### THE MAINE Rx LAW

- 17. The Act, which was not accorded the regular public hearing and public work session processes of the Maine Legislature, enacts a new Chapter 603, entitled "Prescription Drug Access," in Maine Rev. Stat. Ann. Title 22.
- 18. Chapter 603 includes among its principal components (1) a mandatory prescription drug "rebate" program, and (2) penalties for "profiteering" in prescription drugs (including penalties for taking actions to minimize exposure to the Act).

### The Maine Rx Program

- 19. Subchapter I (§ 2681) of the new Chapter 603 establishes the "Maine Rx Program," a prescription drug rebate program administered by the State (specifically, by the Department) for "qualified" Maine residents.
- 20. As administered by the Department, the class of "qualified" Maine residents will include the 325,000 Maine residents who do not have prescription drug coverage under other public or private programs.
- 21. Under the new Maine Rx Program, drug manufacturers are required to remit payments to Maine called "rebates." Maine in turn is required to use these payments to finance discounts provided by retail pharmacies to enrollees in the Maine Rx Program. The Act, through the "rebate" mechanism, thereby effectively transfers to Maine residents a portion of the purchase price received by the manufacturers from their customers (typically wholesalers and distributors). As the Program is being administered by the Department, manufacturers are required to remit these payments regardless of whether their sales occurred outside Maine.
- 22. In particular, Section 2681(3) requires all prescription drug manufacturers and labelers whose drugs are sold in Maine through publicly supported pharmaceutical assistance programs, such as the federal Medicaid program, to enter into

agreements with the Department to provide such "rebates" for their prescription drugs that are dispensed to Maine residents under the Maine Rx Program.

- 23. PhRMA members participate in Medicaid.
- 24. PHRMA members also participate in Maine's Elderly Low-Cost Drug Program (hereinafter the "Elderly LCD Program"), a publicly supported pharmaceutical assistance program.
- 25. The PhRMA members who participate in these publicly supported pharmaceutical assistance program in Maine are thus required by Section 2681(3) to enter into rebate agreements for the Maine Rx Program.
- 26. The Act directs the Commissioner to negotiate the amount of the rebate required from each manufacturer under the obligatory rebate agreement.
- 27. The Act directs the Commissioner to use his "best efforts" to obtain an initial rebate for the Maine Rx Program equal to or greater than the manufacturer's nationwide, statutorily-specified federal Medicaid rebate. Such initial rebates are to take effect beginning January 1, 2001.
- 28. On August 2, 2000 the Commissioner presented pharmaceutical manufacturers with a "Rebate Agreement," for signature no later than November 1, 2000, that requires payment of "the Medicaid Rebate amount" on drugs dispensed under the Maine Rx program.
- 29. The Act also directs the Commissioner to negotiate for further rebates, to take effect no later than October 1, 2001, that are equal to or greater than any discount, rebate or price the manufacturer gives in connection with any federal program.
- 30. If a manufacturer does not enter into a Maine Rx rebate agreement, the Department is directed by Sections 2681(7) and 3174-Y to impose a "prior authorization" requirement on

the manufacturer's drugs that are dispensed—not under the Maine Rx program—but under the entirely distinct federal Medicaid drug program.

- 31. Prior authorization is intended to limit access to a drug. It does so by requiring a physician who wishes to prescribe the drug to Medicaid patients to justify his or her reasons for doing so to the state Medicaid Administrator on a case-by-case basis in order to obtain specific prior permission from the Administrator. Absent such authorization, the Medicaid patient will not receive coverage for the prescription.
- 32. The Act's rebate requirement is conjoined with prohibitions on "profiteering" (discussed *infra* at paragraphs 38-46) that, *inter alia*, prevent manufacturers from rearranging their affairs to minimize their exposure to the rebate requirement while continuing to make their drugs available to Maine residents.
- 33. With the exception of an initial loan from the Trust Fund for a Healthy Maine in fiscal year 2000-01, which must be repaid in fiscal year 2002-03 using rebate revenues collected from manufacturers, the Maine Rx program is to be funded exclusively by the manufacturers' rebate payments through the establishment of the "Maine Dedicated Fund."
- 34. Maine Rx is thus a pass-through program, under which the State itself does not purchase prescription drugs or contribute state funds to subsidize prescription drug purchases by residents covered by the Maine Rx Program.
- 35. In addition to establishing the new Maine Rx Program, the Act (Section 254 ss. 8-A) revises the State's existing, voluntary Elderly LCD Program to make participation mandatory for all manufacturers who participate in Medicaid.
- 36. The Elderly LCD Program receives state funding support.

37. Under the Maine Elderly LCD Program, manufacturers give the State rebates equivalent to those calculated under Medicaid.

### Anti-Profiteering

- 38. Section 2697 declares unlawful the act of "profiteering" in prescription drugs.
- 39. Manufacturers, labelers, and distributors of prescription drugs are deemed to engage in "illegal profiteering" if they: (1) exact or demand an "unconscionable" price; (2) exact or demand prices or terms that lead to an "unjust or unreasonable" profit; (3) "discriminate[] unreasonably" in selling or distributing drugs dispensed in Maine; or (4) intentionally restrict the sale or distribution of drugs in Maine in retaliation for the Act.
- 40. The Act's anti-profiteering prohibitions relating to prices, profits, and preferential terms, Sections 2697(A)-(C), are not by their terms confined to transactions occurring in Maine.
- 41. The Act's fourth anti-profiteering provision, Section 2697(D), precludes manufacturers from rearranging their affairs so as to minimize exposure to the rebate requirement and the anti-profiteering provisions.
- 42. Violations of the anti-profiteering provisions are punishable by, *inter alia*, injunctive relief, treble damages, punitive damages, and civil penalties of up to \$100,000 per violation, plus costs and attorney's fees.
- 43. Violations of the anti-profiteering provisions of the Maine Rx Law are also deemed to violate the Maine Unfair Trade Practices Act.
- 44. Violations of the Maine Unfair Trade Practices Act are punishable by, *inter alia*, injunctive relief, damages, restitution, and civil penalties of up to \$10,000 per violation.

- 45. The Attorney General is responsible for investigating suspected violations of the Act's anti-profiteering provisions and the Maine Unfair Trade Practices Act, and for prosecuting civil violations thereof.
- 46. Violations of the Maine Unfair Trade Practices Act are also subject to private actions for damages, restitution, and equitable relief. Successful plaintiffs may also recover attorney's fees and costs.

#### THE FEDERAL MEDICAID PROGRAM

- 47. Medicaid is a federally mandated, state-administered program that operates under federal guidelines to provide medical care to certain low-income populations. The program is jointly funded by the federal and state governments.
- 48. In 1991 Congress supplemented the federal Medicaid health care program with a rebate program to offset the costs of prescription drug coverage, which states may opt to offer to Medicaid beneficiaries. Omnibus Budget Reconciliation Act ("OBRA") of 1990, enacting § 1927 of the Social Security Act, 42 U.S.C. § 1396r-8.
- 49. Under the Medicaid drug program, drug manufacturers enter into national rebate agreements with the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1396r-8(a)(1). Pursuant to those agreements, manufacturers pay statutorily-calculated rebates directly to each state for their drugs dispensed to Medicaid beneficiaries in the state. 42 U.S.C. § 1396r-8(b), (c); 56 Fed. Reg. 7049 (1991). The states also receive federal Medicaid reimbursement funds for those drugs, and contribute state funds to make up the balance (such that the Medicaid beneficiary makes no more than a nominal payment).
- 50. For each drug, a manufacturer pays the same nationwide Medicaid rebate. 42 U.S.C. § 1396r-8(c)(1)(A).

- 51. The formula for calculation of that rebate is prescribed by statute. 42 U.S.C. § 1396r-8(c)(1).
- 52. The calculation of the rebate starts with the per-unit Average Manufacturer Price ("AMP") paid by wholesalers, taking into account all discounts and price reductions, for drugs in the "retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1).
- 53. The manufacturer's Medicaid rebate for brand-name drugs is the greater of: (1) 15.1% of the AMP or (2) the difference between the AMP and the manufacturer's nationwide "best price." 42 U.S.C. § 1396r-8(c)(1). Thus if any U.S. purchaser (with certain statutory exceptions) pays less than 84.9% of the AMP for the brand-name drug, the Medicaid rebate paid by the manufacturer will be based on that best price. The Medicaid rebate for generic and over-the-counter drugs is 11% of AMP. 42 U.S.C. § 1396r-8(c)(3).

## COUNT I VIOLATION OF COMMERCE CLAUSE Section 2697(2)

- 54. Paragraphs 1-53 are incorporated by reference.
- 55. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.
- 56. The "anti-profiteering" provisions of the Act subject manufacturers to penalties with respect to prices, profits, and terms of sales occurring outside Maine.
- 57. These provisions (Section 2697(2)) violate the Commerce Clause.
  - 58. PhRMA has no adequate remedy at law.

### COUNT II VIOLATION OF COMMERCE CLAUSE Sections 2681(3) and 254 ss8-a

- 59. Paragraphs 1-58 are incorporated by reference.
- 60. The Commerce Clause of the United States Constitution prohibits a state from regulating transactions occurring outside of the state.
- 61. The rebate provisions of the Act effectively regulates the prices received by drug manufacturers from their customers in transactions occurring outside of Maine.
- 62. The rebate provisions (Sections 2681(3) and 254 ss8-A) violates the Commerce Clause.
  - 63. PhRMA has no adequate remedy at law.

## COUNT III VIOLATION OF COMMERCE CLAUSE Section 2681(4)

- 64. Paragraphs 1-63 are incorporated by reference.
- 65. The Commerce Clause prohibits a state from tying instate prices to prices charged in other jurisdictions.
- 66. The rebate provision of the Act ties prices in Maine to prices paid in other jurisdictions by using as benchmarks for the Maine Rx program rebates the nationwide, federal Medicaid rebate, and nationwide rebates and discounts under other federal programs.
- 67. The rebate provision (Section 2681(4)) violates the Commerce Clause.
  - 68. Plaintiff has no adequate remedy at law.

## COUNT IV VIOLATION OF COMMERCE CLAUSE Section 2697(2)(D)

- 69. Paragraphs 1-68 are incorporated by reference.
- 70. The Commerce Clause prohibits a state from interfering with "the mobility of [interstate] commerce."
- 71. The "anti-retaliation" profiteering provision of the Act prohibits drug manufacturers from arranging their interstate distribution channels in response to the Act.
- 72. The "anti-retaliation" profiteering provision (Section 2697(2)(D)) violates the Commerce Clause.
  - 73. PhRMA has no adequate remedy at law.

### COUNT V VIOLATION OF THE SUPREMACY CLAUSE Sections 2681(7) and 3174-Y

- 74. Paragraphs 1-73 are incorporated by reference.
- 75. The Supremacy Clause prohibits state laws that conflict with federal laws and programs.
- 76. The prior authorization provisions of the Act conflicts with federal Medicaid law and the federal Medicaid program by curtailing Maine Medicaid beneficiaries' access to a manufacturer's drugs to punish its failure to finance discounts under the Maine Rx Program.
- 77. The prior authorization provisions (Sections 2681(7) and 3174-Y) violates the Supremacy Clause.
  - 78. PhRMA has no adequate remedy at law.

### COUNT VI VIOLATION OF 42 U.S.C. § 1983

- 79. Paragraphs 1-78 are incorporated by reference.
- 80. The Commissioner and the Attorney General are State officials acting within the scope of their authority in implementing the Act.
- 81. The Act deprives Plaintiff's members of the rights, privileges, and immunities secured by the Commerce Clause and the Supremacy Clause of the U.S. Constitution.
- 82. The Commissioner and the Attorney General are liable to Plaintiff for proper redress under 42 U.S.C. § 1983.

#### RELIEF REQUESTED

WHEREFORE, Plaintiff, Pharmaceutical Research and Manufacturers of America respectfully requests the following relief:

- A. A declaratory judgment, pursuant to 28 U.S.C. § 2201, that Sections 254 ss8-A, 2681(3), 2681(4), 2681(7), 2697, and 3174-Y of the Act violate the United States Constitution and are unenforceable;
- B. A preliminary and permanent injunction enjoining the Defendants from implementing or enforcing the Act;
- C. An order awarding PhRMA's costs and attorneys' fees pursuant to 42 U.S.C. § 1988; and
- D. Such other and further relief as the Court deems just and proper.

# Respectfully submitted,

/s/

Bruce C. Gerrity, Esq. Ann R. Robinson, Esq. Preti, Flaherty, Beliveau, Pachios & Haley, LLC 45 Memorial Circle P.O. Box 1058 Augusta, ME 04332-1058 (207) 623-5300

Attorneys for Plaintiff, Pharmaceutical Research and Manufacturers of America

#### OF COUNSEL:

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Daniel M. Price, Esq.
POWELL, GOLDSTEIN, FRAZER & MURPHY, LLP
1001 Pennsylvania Avenue, N.W.
Sixth Floor
Washington, DC 20004
(202) 347-0066

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

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#### DECLARATION OF RICHARD A. FELDMAN

- 1. My name is Richard A. Feldman. From December 1996 to present, I have served as the Executive Director, Trade and Pharmacy Affairs for Roxane Laboratories, Inc. (hereinafter "Roxane"), an affiliated company of Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Boehringer"). I am responsible for the retail distribution of product for both Roxane and Boehringer (collectively referred to as "Companies").
- 2. Boehringer is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in Ridgefield, Connecticut.

- 3. Roxane is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in Columbus, Ohio.
- 4. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").
- 5. I am knowledgeable about Companies' distribution system, sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Companies' sales of prescription drugs in Maine.
- 6. With the exception of sales transactions described in paragraphs 7 and 8, sales of Companies' prescription drugs occur outside Maine. Companies' warehouses located in Columbus, Ohio and Reno, Nevada receive and fill orders from wholesalers, distributors and warehousing retail chains. The warehouses then ship the orders via common carrier to the requesting entity located at a location outside the state of Maine. Title to the prescription drugs passes to the wholesaler or distributor upon delivery to the carrier. The wholesalers, distributors and warehousing retail chains then sell the prescription drugs to retail stores located throughout the country, including the state of Maine. The wholesalers and distributors do not act on behalf of Companies in the resale of the prescription drugs.
- 7. Companies sell prescription drugs to one warehousing retail chain, Hannaford Brothers, in Scarborough, Maine. Companies ship the prescription drugs and send invoices directly to Hannaford Brothers.
- 8. Bindley Western Drug Company ("Bindley"), a wholesaler based in Indianapolis, Indiana, directs that Companies ship prescription drugs directly to its subsidiary, JE Gould, in Westbrook, Maine. However, Bindley is

invoiced and the title to the drugs shipped to JE Gould passes to Bindley.

9. Other than as described in paragraphs 7 and 8 of this declaration, Companies make no direct sales or shipments of prescription drugs in the State of Maine.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED: August <u>8,</u>2000

/s/
Richard A. Feldman

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

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# DECLARATION OF RUSSEL A. BANTHAM

- 1. My name is Russel A. Bantham. From 1995 to present, I have served as Senior Vice-President and General Counsel of the Pharmaceutical Research and Manufacturers of America ("PhRMA").
- 2. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the

enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Act").

- 3. PhRMA is a non-profit corporation organized and existing under the laws of the State of Delaware. PhRMA's offices are located in Washington, D.C.
- 4. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, happier, and more productive lives. Together these companies account for over 75% of the sales of brand name drugs in the United States.
- 5. PhRMA serves as the pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to, *inter alia*, advancing public policies that foster continued innovation, educating the public about the drug development and discovery process, and promoting a fair and competitive marketplace. PhRMA has represented its members in connection with the Maine Legislature's consideration of legislation regulating prescription drugs, including the legislation ultimately enacted as the Act challenged here.
- 6. All of PhRMA's members have their principal places of business outside Maine.
- 7. PhRMA is authorized by its Board of Directors to bring this suit on behalf of its members. The regulation of prescription drug pricing is of vital concern to PhRMA's members.

### FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

54

DATED: August \_\_, 2000

/s/ Russel A. Bantham

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

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#### DECLARATION OF GEORGE BILYK

- 1. My name is George Bilyk. From August 1996 to present, I have served as the Senior Director, Medicaid and Medicare business of Janssen Pharmaceutica, Inc. ("Janssen"). Prior to my current position, I was Marketing Controller for Janssen from February 1992 until February 1994 and Managed Care finance controller from February 1994 until August 1996.
- 2. Janssen is a corporation organized and existing under the laws of Pennsylvania that maintains its principal place of business in Titusville, New Jersey. Janssen is a wholly

owned subsidiary of Johnson & Johnson, a New Jersey corporation that maintains its principal office in New Brunswick, New Jersey.

- 3. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").
- 4. I am knowledgeable about Janssen's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Janssen's sales of prescription drugs in Maine. All sales of Janssen's prescription drugs occur outside Maine. Janssen's distribution center is located in Franklin, New Jersey from which it fills all orders from wholesalers and distributors. In accordance with Janssen's standard terms and conditions of sale pursuant to which it sells its products to its customers including wholesalers and distributors ("Terms and Conditions"), Janssen delivers the prescription drugs to its wholesalers and distributors at the loading dock of Janssen's distribution center in New Jersey and all sales are FOB, shipping point (i.e. Janssen's distribution center in Franklin, New Jersey). Title and risk of loss passes to the customer at the loading dock in New Jersey. A copy of Janssen's Terms and Conditions is attached to this declaration as Exhibit A. Wholesalers and distributors make payments in New Jersey for the prescription drugs purchased. Wholesalers and distributors re-sell Janssen's prescription drugs to their customers who are located throughout the country, including The wholesalers and customers in the state of Maine. distributors do not act on behalf of Janssen in the resale of the prescription drugs.
- 5. As far as I am aware only two customers, Bindley Western Drug Company and Progressive Distributors, Inc. operate warehouse and distribution facilities in Maine. However, once again, pursuant to Janssen's Terms and

Conditions its sales to these distributors take place in New Jersey.

- 6. When a prior authorization (a "PA") is required for a prescription drug under a plan providing prescription drug coverage, a physician must obtain specific permission from the plan each time the physician wishes to prescribe the drug, or the pharmacist must obtain specific permission from the plan each time the pharmacist is asked to fill a prescription for the drug. Imposition of a prior authorization requirement with respect to a particular drug severely curtails access to the drug for covered patients and sharply reduces the drug's market share and sales, as the PA causes a shift of patients to competing drugs of other manufacturers that are not subject to a PA. Because a PA imposes additional procedural burdens on physicians prescribing the manufacturer's drug and retail pharmacies dispensing it, the effect of a PA is to diminish the manufacturer's goodwill that helped foster demand for its drug over competing drugs produced by other manufacturers, and to shift physician and patient loyalty to those competing drugs, perhaps permanently.
- 7. Based upon Janssen's experience with PA's, if the Maine Department of Human Services imposes PA requirements on Janssen's prescription drugs in the Medicaid program pursuant to § 2681(7) of title 22 of the Maine Revised Statutes, patient access to those drugs will be sharply curtailed and the market share and sales of those drugs will be severely reduced, causing Janssen substantial injury. This injury resulting from a PA authorized by § 2681(7) while the PA is in place is certain to occur and is likely to be substantial.
- 8. Once market share is lost, it is difficult to recover and may never be recovered, as physicians and patients develop loyalty to competing manufacturers' prescription drugs not subject to the PA while the PA on the manufacturer's drug is in place. The result for the manufacturer whose drug is subject to the PA may be a permanent loss of sales, market

share, and good will. This lingering injury to a drug manufacturer resulting from a PA under § 2681(7) is certain to occur and is likely to be substantial.

9. On August 4, 2000 Janssen's sister company, Johnson & Johnson Health Care Systems, received the letter dated August 2, 2000 from Kevin W. Concannon, Commissioner of the State of Maine Department of Human Services, a true copy of which is attached to this declaration as Exhibit B.

FURTHER DECLARANT SAYETH NOT.

I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED:	August 9, 2000				
	/s/				
	George Bilyk				

[Exhibit A]

P.O. Box 401 Raritan, New Jersey 8869-0602

JANSSEN ORTHO-McNEIL Centocor

**PHARMACEUTICA** 

Invoice

Bill To:

Ship To:

Due Date	
Terms of Payment	
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Payments must be received in our bank by the Due Date In order to earn the discount. Please mail your payments 3-5 days prior to the Due Date. No Anticipation.

Post Audit claims will not be honored.

A-061

#### TERMS AND CONDITIONS OF SALE

Any statement contained on any purchases order or similar document, which is not specifically approved or acknowledged in writing by Seller, will not be considered as part of the agreement between the parties.

All orders are subject to acceptance at the home office.

Title, Shipment, Delivery: Title to and Risk of loss of Seller's products passes to Purchaser upon delivery to a common carrier. Seller will pay the cost of freight and insurance to Purchaser's location. Purchaser will pay any costs due to special shipping requests. Seller reserves the right to make shipments in installments as it deems advisable or necessary, and all such installments shipped separately will be separately invoiced and paid.

#### Warranties

Seller warrants that: 1) No article bearing its name (or that of an affiliate) and covered by this invoice is adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, nor is an article which may not, under the provisions of section 404 or 505 of such Act, be introduced into interstate commerce; 2) No article covered by this invoice is produced in violation of any provisions of the Fair Labor Standards Act on 1936, as amended; 3) advertising claims, labels, and circulars employed by it do not violate any provisions of the Federal Trade Commission act, These warranties are in lieu of all other as amended. warranties, expressed or implied, including those of merchant ability and fitness for a particular purpose. request, Buyer will return any allegedly defective products to Seller.

#### Limitation of Liability

In no event will Seller be liable for any direct, indirect, special or consequential damages arising out of or in

connection with the sale or use of products including, without limitation, damages resulting from any breach of any obligation imposed on Seller hereunder or in connection herewith. Consequential damages shall include, without limitation, loss of use, Income or profit, or loss or damage to person or property.

### Invoicing and Pricing

An invoice is rendered by the Customer Service Department to cover each shipment. Merchandise is invoiced at prices in effect on the day the order is received. Prices are subject to change without notice. No claim for rebate on price declines is allowed, nor do we make claims on Buyer or our product on price advances.

All stated terms are from date of invoice, and payment must be received by the due date to earn the cash discount. Neither anticipation nor post audit claims are honored. To qualify for adjustments, report all discrepancies on this invoice within 15 days. No statement will be rendered; kindly remit from this invoice.

#### Taxes

Any tax, duty, custom or other fee of any nature imposed upon this transaction by any federal, state or local government authority shall be paid by Buyer in addition to the price quoted or invoiced. In the event Seller is required to prepay any such tax, Buyer will reimburse Seller.

#### **Prescription Products**

Any product named on this invoice and labeled "Caution: Federal law prohibits dispensing without prescription," is sold for such use only.

#### [Exhibit B]

Angus S. King, Jr. *Governor* 

Kevin W. Concannon *Commissioner* 

# State Of Maine DEPARTMENT OF HUMAN SERVICES Augusta, Maine 04333

August 2, 2000

BARBARA DYMOND JOHNNSON&JOHNSON HEALTH CARE SYSTEMS INC 1000 RT. 202 SOUTH P.O. BOX 300 RARITAN, NJ 088690602

Dear BARBARA DYMOND,

I am writing to you on behalf of the State of Maine, Department of Human Services. I want to inform you about the new Maine Rx Program and invite you to participate in the rebate program for this initiative. I am enclosing a copy of the law, Public Law 1999, chapter 786, for your review.

The Governor and the Legislature passed this new law, during the past legislative session, which goes into effect on January 1, 2001. Under the Maine Rx program the State will serve as a pharmaceutical benefit manager (PBM) for the estimated 325,000 Maine residents who have no prescription drug benefit as part of a private or public health insurance program. Those residents would be eligible to receive a Maine Rx card.

The Maine Rx Program would provide your company's products to an ever growing population and a population that would exceed the current Medicaid population, which is currently 170,000 people. This means greater access to and utilization of your pharmaceuticals.

You will also find a rebate agreement enclosed. I am requesting you sign and return this agreement as soon as possible, but not later than November 1, 2000, so your company's products may be included in the Maine Rx Program for the January 1, 2001 start date. This law also addresses profiteering, unfair trade practices, and requires the Department impose prior authorization requirements in the Medicaid Program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers who do not enter into rebate agreements.

Also to be noted, the names of manufacturers and labelers who do not enter into rebate agreements pursuant to this law are public information. Your company has the opportunity to assist those Maine citizens with a real need for affordable prescription drugs. An added benefit to participating is your company gains nationwide recognition as a participant in the Maine Rx Program. This Program has received nationwide press attention and will continue to do so in the foreseeable future.

Thank you for your continued support of Maine Pharmacy Programs and for your concern for the prescription drug needs of all Maine citizens.

We look forward to working with you, and should you have any questions concerning this Program, feel free to call Jude Walsh, Director, Division of Quality Improvement at (207)287-1815 for our direct assistance.

Sincerely,

/s

Kevin W. Conannon, Commissioner

Enclosures: PL 786

Rebate Agreement

#### MAINE RX PROGRAM REBATE AGREEMENT

#### **BETWEEN**

# THE COMMISSIONER OF THE DEPARTMENT OF HUMAN SERVICES OF THE STATE OF MAINE

#### And -

#### THE MANUFACTURER IDENTIFIED IN SECTION VIII

#### OF THIS AGREEMENT

(Hereinafter referred to as the "Manufacturer")

The Commissioner, on behalf of the State of Maine, and the Manufacturer, on its own behalf for the purposes of complying with Public Law 1999, chapter 786, hereby agree to the following:

#### I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified herein:

- (a) "AVERAGE WHOLESALE PRICE" means the Wholesale Price charged on a specific commodity that is assigned by the drug Manufacturer and is listed in a nationally recognized drug-pricing file.
- (b) "CALENDAR QUARTER" means four times a year. Specifically the first Calendar Quarter will be from January 1, 2001 March 31, 2001. Each successive three-month period shall be a Calendar Quarter.
- (c) "COMMISSIONER" means the Commissioner of the Department of Human Services.

- (d) "DEPARTMENT" means the Department of Human Services.
- (e) "MANUFACTURER" means the entity holding legal title or possession of the National Drug Code (NDC) for the Prescription Drug.
- (f) "NATIONAL DRUG CODE (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this Agreement, the complete 11-digit NDC will be used including the labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or -formulation), and package size code to identify a prescription drug.
- (g) "NET SALES" means Calendar Quarter gross sales revenue less cash discounts allowed and all other price reductions which reduce the actual price paid; and as discussed under the definition of WP.
- (h) "PRESCRIPTION DRUG" means (1) legend drugs, defined as drugs carrying the statement "Caution: Federal Law Prohibits Dispensing Without A Prescription" and (2) any other drugs which by State law or regulation require the prescription of a licensed practitioner for dispensing. For purposes of this Agreement, all Prescription Drugs must be identified by the Manufacturer's labeler code segment of the National Drug Code (NDC).
- (i) "QUALIFIED RESIDENT" means a resident of the State who has obtained from the Department a Maine Rx enrollment card.
- (j) "REBATE AMOUNT" means the Medicaid Rebate amount.
- (k) "REBATE PAYMENT" means, with respect to the Manufacturer's Prescription Drugs, the Calendar Quarter payment by the Manufacturer to the State of Maine

which shall be the sum of the Rebates of each prescription drug (computed for each dosage form and strength of each Prescription Drug) calculated as follows:

- (1) The total number of Units paid under the Maine Rx Program for qualified residents during the Calendar Quarter multiplied by the Rebate amount per Unit.
- (2) Effective January 1, 2001, a percentage equal to the Medicaid Rebate percentage to the State of Maine in effect for the corresponding time period.
- (I) "UNIT" means drug Unit in the lowest identifiable amount (i.e. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the Unit for each dosage form and strength of each Prescription Drug in accordance with instructions developed by the Health Care Financing Administration for purposes of the Federal Medicaid Rebate program under Section 1927 of the Social Security Act.
- (m) "UTILIZATION DATA" means the information regarding the total number of Units of each dosage form and strength of the Manufacturer's Prescription Drugs paid during the Calendar Quarter under the Program. Drugs dispensed prior to January 1, 2001 are excluded. The Utilization Data includes: (1) 11-digit NDC, including package size code; (2) product name; (3) quantity of Units paid during the Calendar Quarter by 11-digit NDC; (4) total number of prescriptions paid during the Calendar Quarter by 11-digit NDC; and (5) total dollar amount paid during the Calendar Quarter by 11-digit NDC.
- (n) "WHOLESALE PRICE (WP)" means, with respect to a Prescription Drug of the Manufacturer for a Calendar Quarter the average price paid by Wholesalers in the United States to the Manufacturer, for ultimate

distribution to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to Wholesalers where the drug is relabeled under that distributor's national drug code). WP includes cash discounts allowed and all other price reductions, which reduce the actual price paid. It is calculated as a weighted average of prices for a Manufacturer's package sizes for each Prescription Drug by the Manufacturer during that Calendar Quarter. Specifically it is calculated as Net Sales divided by number of Units sold, excluding drugs or any other items given away but not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the Units of each drug sold under the bundled arrangement. The V/P for a Calendar Quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjusted the prices actually realized.

(o) "WHOLESALER" means any entity (including a pharmacy or chain of pharmacies) to which the Manufacturer sells the Prescription Drug, but that does not re-label or repackage the Prescription Drug.

#### II. MANUFACTURER'S RESPONSIBILITIES

The Manufacturer agrees to the following:

(a) To calculate and to make a Rebate Payment each Calendar Quarter to the State of Maine for the Manufacturer's Prescription Drugs paid for by the Department pursuant to the Maine Rx Program during a Calendar Quarter under the Maine Rx Program as follows:

Manufacturer's first rebate payment for the Calendar Quarter January 1, 2001 through March 31, 2001 shall be due September 30, 2001, or 30 days after receipt of utilization data pursuant to Section III (a) of this Agreement, whichever is later.

All subsequent Rebate payments will be made by the Manufacturer to the State of Maine within 30 days of the close of each Calendar Quarter, or within 30 days upon receipt of the Utilization. Data pursuant to Section III (a) of this Agreement, whichever is later. Simultaneously, with each Rebate Payment, the Manufacturer will provide the Department with the Manufacturer's most recent price catalog, unless no price changes were made from the previous Calendar Quarter.

- (b) To continue to make a Rebate Payment to the State of Maine on all of its Prescription Drugs as defined in this Agreement so long as this Agreement, or a successor Agreement, is in force and as long as such Prescription Drugs are dispensed under the Manufacturer's NDC. If there are no sales by the Manufacturer during a Calendar Quarter the WP used for the most recent Calendar Quarter in which sales occurred will continue to be used in calculating Rebates.
- (c) The Manufacturer will be responsible for Rebates on claims for prescription drugs that were dispensed within one year of the date that the claim was paid by the Department.
- (d) The Manufacturer agrees to maintain all books, documents, papers, accounting records, and any other evidence pertaining to this Agreement and make such material available at its offices during normal business hours and shall send copies of such material to the Department upon the request of the Department during the period of this Agreement and for a period of two years after the termination of this Agreement. The Manufacturer shall allow inspection of pertinent documents by the Department or any authorized

representative of the State of Maine, and shall furnish copies thereof, if requested.

# III. COMMISSIONER'S RIGHTS AND RESPONSIBILITIES

- (a) The Department, on behalf of the Commissioner, shall send the Utilization Data as defined in this Agreement, to the Manufacturer, by certified mail, return receipt requested, within 60 days following the last day of each Calendar Quarter for qualified residents. The Commissioner, through the Department, shall maintain electronic claims records for the most recent four Calendar Quarters that will permit the Manufacturer to verify through an audit process The Utilization Data provided by the Department.
- (b) The Department shall conduct audits, as it deems necessary to verify rebate calculation and payment.

# IV. DISPUTE RESOLUTION FOR DISCREPANCIES IN REBATE AMOUNTS

Discrepancies in Rebate amounts must be resolved using the following process:

- (a) If there is a discrepancy in the Manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the Manufacturer or labeler, the Department, at the Department's expense, may hire a mutually agreed-upon auditor. If a discrepancy still exists following the audit, the Manufacturer or labeler shall justify the reason for the discrepancy or make payment to the Department for any additional amount due.
- (b) If there is a discrepancy against the interest of the Manufacturer or labeler in the information provided by the Department to the Manufacturer or labeler regarding the Manufacturer's or labeler's Rebate, the Manufacturer or labeler, at the Manufacturer's or labeler's expense,

may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the Department. If a discrepancy still exists following the audit, the Department shall justify the reason for the discrepancy or refund to the Manufacturer any excess payment made by the Manufacturer or labeler.

- (c) Following the procedures established in paragraph a or b, either the Department or the Manufacturer or labeler may request a hearing before the Department of Human Services Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.
- (d) The Manufacturer further agrees that the sole and exclusive means for the presentation of any legal claim against the State arising out of this Agreement shall be in accordance with 5 MRSA section 11001. The Manufacturer further covenants not to initiate legal proceedings in any State or Federal court in addition to, or in lieu of, proceedings under section 11001. This Agreement shall be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine. The Manufacturer consents to personal jurisdiction in the State of Maine.
- (e) Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

#### V. CONFIDENTIALITY PROVISIONS

(a) Commercial or financial information disclosed by the Manufacturer in connection with this Agreement is confidential information, and will not be disclosed by the Commissioner or the Department (including any auditors or agents thereof) in a form which discloses the identity of a specific Manufacturer or Wholesaler, prices

- charged for drugs by such Manufacturer or Wholesaler, in accordance with 42 U.S.C. § 1396r-8(b)(3)(D), 22 M.R.S.A. § 402(3) and Maine Rules of Evidence, Rule 507.
- (b) The Manufacturer will guarantee the protection and confidentiality of the Utilization Date, including the proper care, custody, use and preservation of records, papers, files, communications of the Department and any other information that may reveal information related to the Utilization Data. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Data to auditors who agree to keep such information confidential.
- (c) Notwithstanding the non-renewal or termination of the Agreement for any reason, the confidentiality provisions will remain in full force and effect.

#### VI. TERMINATION

- (a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an indefinite period beginning on January 1, 2001.
- (b) The Manufacturer may terminate the Agreement for any reason, and such termination shall become effective the first day of the first Calendar Quarter period beginning sixty (60) days after the Manufacturer gives written notice requesting termination.
- (c) The Commissioner may terminate the Agreement for any reason, upon sixty- (60) days prior written notice to the Manufacturer.
- (d) The termination of this Agreement by either party will not affect any Rebate payments due to the State of Maine.

(e) In the event that any element of this Agreement is affected by a legislative amendment, including, but not limited to the percentage amount of Rebate required, such amended or revised provisions shall be incorporated by reference within this Agreement and shall supersede any of the conflicting provisions of this Agreement. If either party is unwilling to accept such a change in terms, this Agreement may be terminated pursuant to the terms set out in subsections (a) through (d) above.

#### VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Commissioner will be sent to:

Maine Rx Program
Director of Pharmacy Programs
Bureau of Medical Services, 3rd Floor
11 State House Station
Augusta, ME 04333-0011

Notice to the Manufacturer will be sent to the address provided to the Department by the Manufacturer.

- (b) In the event of a transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner subject to the conditions specified in this Agreement.
- (c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, without any effect on any other provision.

- (d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Commissioner under the Constitution, the Social Security Act, other Federal laws or State laws.
- (e) The terms "Department: and "Manufacturer" incorporate any contractors or agents thereof, which fulfill responsibilities pursuant to this Agreement unless specifically provided for in the Rebate Agreement.
- (f) This Agreement will not be altered except by an amendment in writing signed by both parties and except as indicated in subsection VI (e). No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by a duly appointed representative of the Manufacturer, and the Commissioner, and approved by the Office of the Attorney General.
- (g) In the event that a due date falls on a weekend, or a Federal or State holiday, the report or other item will be due on the first business day following that weekend or holiday.

#### VIII. MANUFACTURER'S ACCEPTANCE

Ι,	hereby agree to the terms					
(Name of Authorized Representation of this Agreement for the labeler(s):		s) and				
(Labeler Name)	(Code)					
(Labeler Name)	(Code)					
(Labeler Name)	(Code)					

	/4					
(Labeler Name)	(Code)					
(Signature)	(Title)					
Date:						
IX. COMMISSIONER'S	CERTIFICATION					
This is to certify that participant in the Maine effective		is a Program				
Christine Zukas-Lessard	DATE:					
Acting Director, Bureau of N For the Commissioner	Medical Services					

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE

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#### DECLARATION OF THOMAS M. MCPHILLIPS

- 1. My name is Thomas M. McPhillips. I serve as the Senior Director of the U.S. Trade Group of Pfizer Inc. ("Pfizer").
- 2. Pfizer is a corporation organized and existing under the laws of Delaware that maintains its principal place of business in New York, New York.
- 3. I am filing this Declaration in support of PhRMA's Motion for a Preliminary Injunction which seeks to enjoin the enforcement of the Act to Establish Fairer Pricing for

Prescription Drugs, 2000 Me. Legis. Ch. 786 (S.P. 1026) (L.D. 2599) (West) (hereinafter, the "Maine Rx Law").

- 4. I am knowledgeable about Pfizer's distribution system, including its sales arrangements with wholesalers and other customers including the Federal government, and specifically, the extent of Pfizer's sales of prescription drugs in Maine.
- 5. With the exception of sales transactions described in paragraph 7, sales of Pfizer's prescription drugs occur outside The Pfizer warehouses located in New Jersey. Maine. Tennessee and California fill orders from wholesalers and direct customers. In accordance with its standard published terms of sales to wholesalers and direct customers a copy of which is attached as Exhibit A to this declaration, Pfizer receives orders from wholesalers and other customers by electronic medium, facsimile, mail or telephone at Pfizer's logistics center in Memphis, Tennessee and then routes the orders to appropriate warehouses for processing. warehouses then ship the orders via common carrier to the customers. The terms of sale state that title to the prescription drugs passes to the wholesaler or direct customer upon delivery to the carrier which is when a sale is recognized. The wholesalers then sell the prescription drugs to their customers who are located throughout the country, including customers in the state of Maine. The wholesaler and distributors do not act on behalf of Pfizer in the resale of the prescription drugs. Direct customers include pharmacies, hospitals, public health clinics and dispensing pharmacies. These customers dispense product based on physician's orders and prescriptions to patients located throughout the United States.
- 6. Warner Lambert Company is a wholly owned subsidiary of Pfizer. Warner Lambert's operating division, Parke-Davis sells prescription drugs outside of Maine. The Parke-Davis warehouses located in Illinois and Pennsylvania fill orders from wholesalers and direct customers. In accordance with Parke- Davis' standard terms of sales to wholesalers and